



**International Academy
of Compounding Pharmacists**

P.O. Box 1365
Sugar Land, Texas 77487

281/933-8400 voice
281/495-0602 fax
1-800-927-4227

www.iacprx.org
iacpinfo@iacprx.org

October 13, 2000

Ms. Anne Henig
Center for Drug Evaluation and Research (HFD-006)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Ms. Henig:

The International Academy of Compounding Pharmacists has requested time to present at the public hearing on the Prescription Drug Marketing Act on October 27, 2000. In preparation for that hearing, I recently called you with several questions about the hearing process and format. You suggested that I call Peg O'Rourke because you could only provide me with directions to the hearing location. I did call Ms. O'Rourke that same day but unfortunately, she was not able to answer my questions either. Therefore, I am hoping that by putting my questions in writing you can see that they get the attention of someone who can answer them and get back to me prior to the meeting.

First, will IACP be notified in advance what time we will be speaking and how much time will be allotted for our presentation? Will we need to come and sit through the entire hearing from 8:30 a.m. until 4:30 p.m.? As a non-profit association, IACP seeks to minimize costs. Therefore, we would like to know in advance when our Washington representatives will need to be present. The length of time given for the presentation is also critical. If we prepare a 20-minute presentation and then only have five minutes to speak, it will be difficult at the last minute prior to speaking to ensure the most significant information is presented.

Second, what is the format of the meeting? Will one large group of FDA officials listen to speakers in sequence or will there be smaller panels of FDA officials or break-

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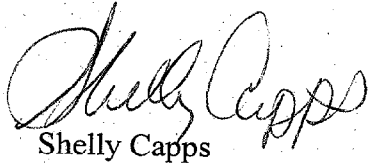
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out panels listening to presenters simultaneously? The second format would allow more opportunity for interactive dialogue and questioning. IACP's presentation will be prepared differently based on the format of this hearing. Therefore, it is important that these questions be answered as soon as possible.

IACP wants to effectively and efficiently present at the hearing on October 27. I appreciate your help in gaining more insight about this hearing so that we can provide valuable and relevant information to FDA.

Sincerely,

A handwritten signature in cursive script, reading "Shelly Capps".

Shelly Capps

Executive Director